

§ 866.3060 *Blastomyces dermatitidis* serological reagents.

(a) *Identification.* *Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Blastomyces dermatitidis* in serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis*. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3065 *Bordetella* spp. serological reagents.

(a) *Identification.* *Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough (*Bordetella pertussis*) and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.3085 *Brucella* spp. serological reagents.

(a) *Identification.* *Brucella* spp. serological reagents are devices that consist of antigens and antisera used for

serological identification of *Brucella* spp. from cultured isolates derived from clinical specimens or to identify antibodies to *Brucella* spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus *Brucella* and provides epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3110 *Campylobacter fetus* serological reagents.

(a) *Identification.* *Campylobacter fetus* serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium and provides epidemiological information on these diseases. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and is sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

(b) *Classification.* Class I (general controls).

§ 866.3120 *Chlamydia* serological reagents.

(a) *Identification.* *Chlamydia* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to chlamydia in serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye used to identify chlamydia directly from clinical specimens or cultured isolates derived from

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clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) *Classification*. Class I (general controls).

§ 866.3125 *Citrobacter* spp. serological reagents.

(a) *Identification*. *Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25046, June 12, 1989; 66 FR 38791, July 25, 2001]

§ 866.3135 *Coccidioides immitis* serological reagents.

(a) *Identification*. *Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Coccidioides immitis* in serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on diseases caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures

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in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59226, Nov. 3, 1998]

§ 866.3140 *Corynebacterium* spp. serological reagents.

(a) *Identification*. *Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus, *Corynebacterium diphtheriae*, causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin, and are either nonpathogenic or have an uncertain role.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2311, Jan. 14, 2000]

§ 866.3145 Coxsackievirus serological reagents.

(a) *Identification*. Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to coxsackievirus in serum. Additionally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye that are used to identify coxsackievirus from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).